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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Werner Seeger

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CLARK & BRODY

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EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1618

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/534,885	<b>Applicant(s)</b> SEEGER ET AL.	
	<b>Examiner</b> ERIC E. SILVERMAN	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2009 and 24 November 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 9-18 is/are pending in the application.
- 4a) Of the above claim(s) 13-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5 and 9-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/26/09 3/30/09</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicants' responses to the restriction and election requirements, filed 8/7/2009 and 11/24/2009, are noted. Applicants elected Group I, drawn to biodegradable colloidal particles, with traverse. The traverse was on the basis that the single inventive concept running through all the claims is the colloidal particles of claim 1. The argument is unpersuasive because the colloidal particles of claim 1 are known in the art, and thus cannot be a special technical feature that unites all of the claims.

By the amendment to claim 1, Applicants also constructively elected the species of comb polymers that is now recited in claim 1. If claims to additional species are added later, such claims should be indicated as "withdrawn" for not reading on the elected species.

Pursuant to Applicants' submission, claims 1, 3-5, and 9-12 are treated on the merits. Claims 13-18 are withdrawn. Claims 1, 3-5, and 9-18 are pending.

### ***Information Disclosure Statement***

The Wittmar reference, cited in the information disclosure statement filed 8/29/2009, was not considered because the copy received by the office is illegible. The reference will be considered if Applicants re-submit this reference in legible form, preferably as a blown-up copy with reasonably sized characters. Various foreign references were not considered because they were accompanied by neither a statement by Applicant of the reason why they were cited, nor a translation.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 requires "as a stabilizer, at least one negatively charged organic base, which can be a Lewis or Bronsted base, or the corresponding acid thereof, which can be a Lewis or Bronsted acid." This language is confusing because it is not clear if the stabilizer must be a Lewis or Bronsted acid or base, or if it is optional that the stabilizer be a Lewis or Bronsted acid or base. The language is also confusing because the claim further requires that "the acid groups of the stabilizer [be] available in excess or deficiency in relation to the amino groups of the comb polymer." If the stabilizer is a base, particularly a Lewis or Bronsted base, it will not normally have acid groups. This language makes the identity of the stabilizer unclear. Further, the language appears to be unnecessary because the claim later requires the stabilizer to be "a combination of CMC and one or more pharmaceutically active species." A clarifying amendment would be helpful.

Claim 1 also requires that "the colloidal particles feature a positive or negative zeta potential." A zeta potential is not a feature of a particle, but of a colloidal system. The zeta potential represents the potential difference between the dispersion medium at a point away from a dispersed particle, and the electronic potential of the dispersion medium associated with the dispersed particle. Properly, the zeta potential is a property of a dispersion, not of a dispersed particle. Because the claim is drawn to a particle and

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not to a dispersion of particles, there need not be a zeta potential. But even if there is a zeta potential, it is a feature of the entire colloidal dispersion, not a feature of the particles alone. This issue also renders claims 11 and 12 problematic, because the zeta potential depends not just on the nature of the particles, but also on the nature of the dispersant. The claims, however, are not drawn to a dispersion. Thus it is not clear if these claims are an attempt to limit the nature of the dispersant to one that will give the recited zeta potentials when the particles are dispersed therein. If so, it is not readily clear what dispersants will yield this property.

Claim 1 further includes the undefined variables x, y, z, n, and m. These undefined variables render the claim indefinite.

Claim 5 uses the trademark "Iloprost®." The use of trademarks in a claim should only be permitted when there is no other way to claim the invention. This is because the trademark identifies the source of goods, but not the nature of goods; the identity of an item associated with a trademark may change over time. Here, the claim should be amended so that the active substance is identified by its common name, or if it does not have a common name, by its IUPAC standard name. There is no reason why the active substance cannot be adequately identified without using a trademark. If iloprost is not a trademark, then the term may be used in the claim, but it should not be identified as a registered trademark.

It is unclear if claim 10 is a product by process claim. The claim appears recites process steps, to wit, "which were quaternized via the addition of an organic acid and stabilized via the corresponding negatively charged organic base which resulted from

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this." Process steps in product by process claims should be written in the present tense. For clarity, the Examiner suggests adding language such as "produced by a process comprising" followed by the appropriate process steps. In particular, it is not clear what the step of "stabiliz[ing]" includes, or if stabilizing is a step at all. The term "stabilized" in the claim lacks a clear object; what is it that is being stabilized? Is the object of "stabilized" the particles, the quaternary amino groups, the acid, or something else? Whatever the intended object of "stabilized," objects are stabilized by addition of stabilizers, not via such addition as claimed. Also, what does it mean to be "quaternized via the addition of an organic acid?" Is this supposed to read "quaternized by addition of an organic acid"? Is the organic acid in this claim the same as the "corresponding acid thereof" in claim 1? As the claim stands, is it not clear whether or not the claim is a product by process claim. Furthermore, the antecedent of what seems to be a pronominal "this" in the phrase "which resulted from this" is uncertain.

All of the claims depending on claim 1 are also rejected by virtue of their dependence, which incorporates by reference the indefinite subject matter of claim 1 without remedying the problems.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kissel et al. "Protein Delivery Systems Based on Branched Biodegradable Polyesters" ("Kissel") in view of US 6,908,626 ("the '626 patent").

*1. The Kissel reference is competent prior art under 102(b) and 102(a)*

The Kissel reference is a report of a proceeding of the 29th Annual Meeting of the Controlled Release Society in 2002, but the reference specifies neither the month nor day of the meeting. The Eurand press release dated 7/23/2002 is a report of an award presented at this same meeting. The press release could not have issued before the meeting, and thus the Office concludes that the Kissel reference is a report of a public disclosure on or before 7/23/2002. The date of filing for a patent in this country for the claimed invention is no earlier than the date of filing of PCT/DE03/03787, which is 11/14/2003. Because the Kissel reference is more than one year prior to the filing date for a patent in this country, it is competent under 102(b). In the absence of other evidence, the invention is deemed to have been made on the original filing date of the earliest priority document, 11/15/2002. The Kissel reference is before that date and is also by another, making it competent prior art under 102(a).

*2. The prior art and the reason for the rejection*

The Kissel reference teaches particles comprising the DEAPA-PVAL-g-PLGA branched polyesters of instant claims. Abstract, experimental methods. Note that while Figure 1 shows the PLLA graft copolymer, the article also describes the PLGA graft copolymer of the claims. The particles are prepared with TRIS buffer (a phosphoric acid

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of claim 3) and insulin (a protein, thus comprising a carboxylic acid at at least its C-terminus) or trypsin/insulin. The particles are described as nanoparticles. Abstract.

What is lacking is CMC.

The '626 patent teaches CMC (carboxymethyl cellulose) and its salts as surface stabilizers for nanoparticle compositions. Claims 1 and 20.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use CMC with the particles of Kissel. Motivation comes from the '626 patent's teaching that CMC would act to stabilize dispersions of nanoparticles. The expected result would be additional stability in pharmaceutical dispersions, which the artisan would view as advantageous.

Claims 1, 3-5, and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kissel in view of the '626 patent, as applied above, and in further view of US 5,049,582 ("the '582 patent").

What is lacking from Kissel and the '626 patent is iloprost.

The '528 patent teaches that iloprost is useful in treating or preventing kidney damage. Claim 3.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to include iloprost in the drug delivery composition of Kissel and the '626 patent. Obviousness stems from the known pharmaceutical advantages of iloprost, and the artisan would expect to succeed in creating a composition that treats or prevents kidney damage.

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***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/  
Primary Examiner, Art Unit 1618